COMMENTS: ATSDR HEALTH CONSULTATION – PUBLIC COMMENT VERSION, EVALUATIOIN OF COMMUNITY-WIDE ASBESTOS EXPOSURES, EL DORADO HILLS NATURALLY-OCCURRING ASBESTOS SITE (March 29, 2010)

The draft Health Consultation addresses health risks arising from exposure to naturally-occurring asbestos (NOA) in the community of El Dorado Hills, CA, which is in the foothills of the Sierra Nevada Mountains. This Health Consultation is based primarily on data on personal exposures to NOA during various recreational activities at public schools and parks in the community. These activity-based exposure data, along with concurrent data on ambient air NOA concentrations, were collected by U.S. EPA Region 9 during 11 days of simulated recreational activities in the fall of 2004. ATSDR used these personal exposure and ambient background data to construct scenarios estimating 24 hour/day NOA exposures for El Dorado Hills residents engaging in low, medium and high levels of recreational activities. These exposures were then incorporated into a series of asbestos risk assessment models to generate a range of excess lifetime cancer risk estimates accruing to residents as a result of their NOA exposures in the community; use of one of the models required that ATSDR perform additional analytical work on a subset of the original U.S. EPA field samples. This extensive risk assessment analysis is presented as the primary focus of the draft Health Consultation and forms the basis for ATSDR's conclusions regarding risk and the advisability of conducting a Health Study in the community.

ATSDR has produced a thorough, detailed assessment of NOA-related cancer risks which provides important health risk information to this community and, by extension, to other foothill communities where NOA is present. It is clear that ATSDR performed a more rigorous, comprehensive cancer risk assessment than usual to support this draft Health Consultation. In addition to utilizing extensive personal monitoring data collected by U.S. EPA on the specific exposures addressed in the risk assessment, ATSDR commissioned additional analytical work and employed a number of different models for assessing asbestos-related cancer risks arising from those activities, as well as background exposures.

MAJOR ISSUE – CONCLUSION 1 GETS LOST

The report, as written in its current draft, does not convey to the reader a complete understanding of the magnitude of health risks, both cancer and non-cancer, from naturally occurring asbestos (NOA) that are facing the El Dorado Hills community (and by extension other foothill communities similarly exposed to NOA). The risk message, although well supported by the quantitative results of the technical assessment, is weakened by a discussion of uncertainties that over-emphasizes the possibility that actual cancer risks in from NOA are significantly lower than shown by the analysis. Furthermore, the draft report also excludes, or down-plays, information from other sources that support the conclusion of significant health risks in the community due to NOA exposure.

A revised discussion of uncertainty and consideration of other pertinent risk information are crucial because they affect the take-away message of the report. In its current form, with the discussion of uncertainty so strongly one-sided and with supporting information from other sources incompletely presented, an important conclusion of the draft Health Consultation gets lost. Namely, Conclusion 1 that "***Breathing in naturally occurring asbestos (NOA) in the El Dorado Hills area, over a lifetime, has the potential to harm people's health***" gets overshadowed, especially by the many comments on uncertainty which give the impression the results of this cancer risk assessment are not to be believed.

The community and the media have already interpreted this draft Health Consultation to mean there is no concern for potential health threats from NOA in this and other communities (including the Clear Creek Management Area). Three aspects of the draft report reinforce this interpretation for interested parties: (1) Conclusion 2 that performing a Health Study would not provide helpful information, especially the statement that "... we do not expect observable increases in disease", (2) lack of detail on and only limited discussion about epidemiological studies around the world showing disease from environmental, non-occupational asbestos exposures, and (3) the one-sided discussion and many statements emphasizing the potential for risk assessment to overestimate risk. Although the quantitative cancer risk assessment shows potentially significant cancer risks from NOA exposure in the community, this message is lost in the overall benign tone of the draft report.

1. Present A More Balanced Discussion of Risk Assessment Uncertainties:

The report needs to present a more balanced view of the uncertainty in the risk assessment. The discussion of uncertainty is disproportionately slanted towards concluding that cancer risks are overestimated by the assessment (i.e., that the true risks of asbestos-related cancer are significantly lower than indicted by the risk assessment). Thus, much of the discussion appears to down-play cancer risks from NOA exposures and/or call into question the strength of the risk assessment and or risk assessment process. For example:

- "...*theoretical* risk..." (pp. v, vi)
- "...*considerable uncertainty*..." (p. v)
- "...a *general sense* of the increased risk..." (p. v)
- "... *great deal of uncertainty*..." (p. 12)

If ATSDR feels the results of this cancer risk assessment contain significantly less certainty than most risk assessments or than other asbestos exposure risk assessments, this conclusion should be stated explicitly and supporting details for this position should be presented and referenced.

Based on our experience, we conclude this is a much stronger, more robust cancer risk assessment than implied by the many comments on uncertainty in the manuscript. We also believe there are reasons that asbestos-related health risks actually may be underestimated by the draft report. These conclusions are supported by a number of factors:

- ***Reliable exposure concentration data.*** The cancer risks calculated for recreational activities are based on personal exposure monitoring data (measurements of asbestos concentrations in the breathing zone) collected during the exact activities and at the exact same locations that are the focus of the cancer risk assessment. This is in contrast to many risk assessments which rely on exposure concentrations mathematically modeled from contaminant concentrations in environmental media (e.g., inhalation exposure to soil contamination is often based on models of fugitive dust generation or results from stationary air monitors). Thus, the exposure assessment underlying this risk assessment is based on measurements of actual breathing zone concentrations during the specific activities included in the assessment – this is a more rigorous quantification of exposure than appears in most risk assessments.

  This observation is supported by comments from Peer Reviewer #2 who expressed the opinion that "[t]his study is actually a model of the types of exposure data that should be routinely collected in health consultations." U.S. EPA's Science Advisory Board has also made a number of

observations acknowledging the advantages of basing exposure estimates on breathing zone monitoring data.

- ***Reliable exposure frequency & duration assumptions.*** The recreational exposure scenarios in this cancer risk assessment are based on realistic exposure frequency and duration assumptions. The validity of these frequency and duration assumptions were confirmed through a review by the very same community that is the focus of the assessment. In addition, these frequency and duration assumptions are consistent with statistical data on children's recreational activities as presented in the Child-Specific Exposure Factors Handbook (EPA/600/R-06/096F, September, 2008). This is in contrast to many risk assessments which rely on generic or national default assumptions about exposure frequency and duration.

- ***Concurrence of risk model results.*** A somewhat unique feature of this risk assessment is the application of a number of different cancer risk assessment models to the same exposure scenarios. The fact that cancer risk estimates developed using these different models were all within a fairly tight (for risk assessment) range gives additional credibility to the results.

  Risk assessors generally feel that when similar results are obtained using different models this strengthens confidence in the risk assessment conclusions. Given how different the various models used in this risk assessment were, the fact they all predicted cancer risks within a fairly narrow range provides additional support to the conclusion that risks from NOA in the community are significant.

  With respect to this issue, Region 9 notes that even Peer Reviewer #2, whose comments generally emphasized the uncertainty in risk assessment, commented that "...the coherence in results [from the various risk assessment methods] needs further discussion and *emphasis*."

- ***Lack of non-cancer risk estimates.*** While the cancer risk assessment in this Health Consultation is robust, non-cancer risks are not estimated at all in the risk assessment. Nor is there much discussion of non-cancer risks to the community. This is an important deficit because non-cancer health effects (e.g., pleural abnormalities, asbestosis) have been observed in a number of situations involving low-level exposures to asbestos. In fact, the high incidence of pleural abnormalities in Libby MT and elsewhere suggest that non-cancer health effects from asbestos exposure may be more prominent (i.e., create higher risk) than asbestos-related cancers in NOA-exposed populations. In addition, follow-up studies of workers at the O.M. Scott, Marysville plant are also showing pleural abnormalities occurring from relatively low level exposures (Rohs AM, Lockey JE, et al., Low-Level Fiber-Induced Radiographic Changes Caused by Libby Vermiculite, A 25-Year Follow-up Study. Am J Respir Crit Care Med 177:630-637, 2008).

  The draft Health Consultation does make the observation that asbestos-related non-cancer health effects (e.g., pleural abnormalities) "are often seen in asbestos-exposed communities". This is an important observation for the residents of El Dorado Hills and should be more fully discussed.

  We recognize that there are currently no well-accepted, peer-reviewed toxicity values for quantifying non-cancer risks from asbestos exposures, but feel there is sufficient information in the published literature for a detailed discussion of potential non-cancer risks.

It is our opinion that the lack of a non-cancer risk estimate makes it likely that actual risks are underestimated, rather than overestimated, by this risk assessment.

With respect to the level of uncertainty in asbestos health risk assessment, it is noteworthy to us that ATSDR produced an earlier Health Consultation addressing NOA exposures in the El Dorado community that did not contain similar discussions of uncertainties and did not appear to question the cancer risk assessment results supporting that Health Consultation. In fact, the Uncertainties section of the January 2006 Health Consultation for "Asbestos Exposures at Oak Ridge High School" concludes that the EPA 1986 risk model, which is used in both Health Consultations, may underestimate actual cancer risk.

2. More Thorough Consideration of Data From Other Sources:

There are published studies, and other information, not cited in the draft Health Consultation which support the conclusion that communities exposed to NOA in California, and elsewhere, are at significantly elevated risk for asbestos-related diseases. We feel that both the quality of the Health Consultation and the message for the El Dorado Hills community would benefit from a more thorough discussion of this information, including:

- ***Schenker study.*** The "Schenker study" is a publication by epidemiologists at the University of California Davis showing an association between residential exposure to sources of environmental asbestos in California and incidence of mesothelioma (Pan X, Day HW, Wang W, Beckett LA, Schenker MB. Residential proximity to naturally occurring asbestos and mesothelioma risk in California. Am J Respir Crit Care Med, 172(8):1019-1025, 2005). This study is referenced in the draft Health Consultation but only a passing reference is made to it and there is no discussion of its findings. It concluded that residential proximity to NOA is significantly associated with increased risk of mesothelioma, as borne out by actual cancers reported to the California Cancer Registry. This is an important study which is directly germane to the question of whether asbestos-related cancer risks are elevated in areas such as El Dorado Hills; it therefore deserves a thorough presentation and discussion in the Health Consultation.

- ***California Cancer Registry Data.*** The general tone of the report downplays the possibility that exposures to NOA are causing health effects in affected communities. In this context it is interesting to note that 4 of the 5 California counties noted in the report as having "the potential for asbestos exposures from serpentine gravel roads or roads cutting through natural serpentine" (p. 3) are within the upper quartile of California counties with the highest rates for invasive cancer of the pleura (the California Cancer Registry classifies pleural mesothelioma as a "pleural invasive cancer" for their website). These 4 counties are El Dorado, Calavaras, Napa and Amador. According to the California Cancer Registry website, Napa has the highest invasive pleural cancer rate in California, with Alpine-Amador-Calavaras (grouped) the 6th highest and El Dorado the 8th highest (cancer rate data for years 1988-2007). Lake County, another county identified by the California Air Resources Board (CARB) and the draft report (p. 40) as having a high potential for NOA exposures, has the 3rd highest rate of invasive pleural cancer in California. Placer County, where CARB air sampling indicated ambient asbestos exposures similar to those in El Dorado (P. 40), is also in the upper quartile for invasive pleural cancer rates and ranks 10th highest of the California counties. Information on these associations has been published (Case BW, Abraham JL. Heterogeneity of exposure and attribution of mesothelioma: Trends and strategies in two American counties. J Physics: Conf Series 151, 2009).

3. Provide Additional Supporting Details:

Many important issues or observations in the report are incompletely discussed or referenced. The report should provide additional details and/or specific references when discussing some of the more important assumptions, calculations, interpretations and conclusions of the risk assessment.

- ***Background ambient air concentration.*** The text on pages 32-33 states the "background concentration" of 4x10-3 PCME f/cc for dry periods based on U.S. EPA's reference station data (which was collected during a dry period). The average of U.S. EPA's reference station data was 0.0008 PCME f/cc – no details are given as to how the assumed background exposure concentration was derived from this value.

- ***Child exposure concentrations.*** Table 3 notes that stationary monitor data ("observer hi-vol") were used as the exposure point concentrations for the child-recess, child-digging and child-physical education scenarios. In contrast, data from personal monitors were used for the exposure point concentrations for the other child-activity scenarios (e.g., bicycling, asphalt courts). The text should explain why personal exposure data were not used for all child-activity scenarios.

- ***Comparison to exposures causing disease.*** The discussion under Conclusion 2 states that NOA exposures in El Dorado Hills are lower than those responsible for causing disease in other communities where NOA is present. However, no data are presented - nor is there a detailed discussion - to support this statement. Ambient air community monitoring data from Libby MT, where a large percentage of the non-worker population exhibits signs of asbestos-related pleural changes, suggests that similar low-level exposures may indeed cause observable health effects. The situation in Libby also conflicts with the implication of the statement under Conclusion 2 about worker and community exposures ("Although theoretical risk was increased, potential exposures are generally orders of magnitude lower than those experienced by former asbestos workers").

- ***Alternate application of Cal/EPA risk method.*** The results of the alternate application of the Cal/EPA risk method, in which the Cal/EPA inhalation unit risk is applied to measured PCME data rather than PCME concentrations calculated using the 320 conversion factor, should be presented in Table 4 along-side the results of the other risk assessments methods.

4. "Asbestos" Terminology & Characterization:

The terminology surrounding asbestos exposures and related health effects is complicated, controversial and is used by some stakeholders to obfuscate potential health issues (for example by implying that only asbestiform habits of the 6 regulated fibers are toxic). For this reason extreme care should be taken to only use scientifically appropriate terminology. The definitions/terms differ depending upon whether you are a geologist, laboratory analyst, health professional or a regulator. More often than not these differences are significant and remain contentious, even more so when it involves NOA. For example some might define asbestos as limited to the 6 asbestiform types listed under OSHA or EPA regulations whereas the geologists' definition might expand the amphibole definition to 60 or 70 types. The health professional is not limited to the 6 regulatory types but is concerned about any amphibole (whether asbestiform, non asbestiform or transitional structures) that might cause adverse health effects. For this

reason extreme care should be taken to only use appropriate terms and avoid terms such as one which is used in the report, "true asbestos".

ATSDR could look to the U.S. Geologic Service report on amphiboles in El Dorado Hills (Meeker GP, Lowers HA, Swayze GA, Van Gosen BS, Sutley SJ, Brownfield IK. Mineralogy and morphology of amphiboles observed in soils and rocks in El Dorado Hills, California. U.S. Geological Survey Open-File Report 2006-1362. December 2006) for guidance on appropriate terminology. The USGS report highlights the scientific complexity when dealing with naturally occurring amphiboles particularly the difference between the occupational situations that involved usually 3 types of asbestos (chrysotile, amosite and crocidolite) and the NOA exposure to many more forms of amphibole. A more expansive discussion of NOA as described in the USGS report is recommended as the report seems to concentrate on occupational exposures rather than the situation in El Dorado Hills with NOA amphiboles. It would also help the reader to know that there is also mortality and disease from exposure to non occupational asbestos (see various articles from the Mediterranean area, Cappadocia, Wittenoom and even Libby).

5. Conclusion 2:

We feel that a well designed study of disease rates in the community could potentially yield valuable information on the risks of NOA exposure, not only for El Dorado Hills but also for other foothill communities throughout California where similar exposures are occurring or may occur in the future. It is true, as noted in the draft Health Consultation, that many current El Dorado Hills residents may be too new to the community to have developed asbestos-related diseases at present (due to the very long latency characteristic of these diseases). However, a study focused on the many long-term residents of El Dorado County may indeed find significantly elevated incidences of asbestos-related diseases. Such a result is already suggested by the Schenker study (see details above) and would be an important public health finding both for newer El Dorado residents and for those of other foothill communities undergoing similar rapid population growth.

- ***Health study.*** One supporting statement to Conclusion 2 is that a "health study would not conclusively state that NOA caused a specific person's health condition" (p. vi); this statement deserves comment. First, this is true of <u>any</u> health study. It is rare that a health study is able to make an unequivocal cause-effect link between a measured environmental exposure and specific cases of disease; usually the best that can be done is to observe if there is an association between increased disease rates and elevated exposures. Second, asbestos exposure is well recognized as almost the only cause of at least two specific health conditions (mesothelioma and pleural plaques); therefore finding either condition in El Dorado residents who have not worked with asbestos would be a very strong indication that NOA exposures *are* causing disease in the community. In this regard, a health study of exposure to asbestos has perhaps the greatest chance of any health study to attribute causation; more so than for most hazardous chemical exposure situations.

- ***Health study.*** Another supporting statement to Conclusion 2 is that "[e]ven if exposure where high enough to cause disease, it takes decades for symptoms to appear. Therefore health conditions may not be detected at this time." This observation assumes that exposures began recently and ignores the many people who have lived in El Dorado for decades. It is true that the population has increased significantly over the last 10-15 years, but there are significant numbers of people who have lived there for decades.

6. Presentation of Risk Comparisons:

Some of the risk comparisons seem inappropriately intended to trivialize risk estimation (e.g., "risk of being hit by a meteor while walking on the sidewalk") or not germane to a Health Consultation for an environmental exposure. It would be useful, and informative for the community, to include some comparisons to risk estimates generated for other Health Consultations and/or at Superfund sites. It would be especially useful if these comparisons indicated whether the risks at these other sites were judged sufficiently high to warrant a health study by ATSDR and/or a remedial (clean up) action by EPA.

Another good comparison would be to cancer risks from indoor exposures to naturally-occurring radon gas. This risk seems especially germane because, similar to NOA cancer risk, it arises from exposure to a naturally-occurring agent (radon), the level of exposure and distribution of which varies depending on local geology (as is the case with NOA). If the radon example is used it would be informative to note that U.S. EPA and other public health agencies have radon awareness and assessment programs in place because of the high risks posed by this naturally-occurring chemical threat.

MISCELLANEOUS / EDITORIAL COMMENTS

Exposure point concentrations. The term "structure level" appears to be used to mean the concentration of asbestos which the risk assessment assumes is breathed during the various activities that form the exposure scenarios. This term is confusing and is not customarily used in risk assessment. A more typical term would be "exposure point concentration", or the term used in ATSDR's Health Consultation for Oak Ridge High School, "asbestos fiber concentration".

Distribution of NOA exposures in El Dorado Hills. Various comments in the report imply that NOA exposures may be very limited in the community. It is important for the community to understand that U.S. EPA's ABS activities, which showed significant exposures, did not take place directly on NOA deposits or veins. Rather, as documented in the USGS report, the amphibole exposures monitored by the ABS personal exposure samplers resulted from weathering and dispersion of NOA in the community (USGS Open-File Report 2006-1362).

Community versus worker exposures. The discussion of community versus worker exposures on page 12 is misleading in downplaying the frequency and duration of community exposures. There are 2 statements alleging that community exposures are shorter and more infrequent than worker exposures. Given that PCME amphiboles were observed in every ambient air sample collected by U.S. EPA in the El Dorado Hills community, this statement is not supported by the data. For a stay-at-home resident, the data show that exposure could be 24 hours per day, assuming that asbestos is not somehow filtered as ambient air becomes indoor air. And, although there are many newer residents in the community, some El Dorado residents have lived there for decades – census data show that the largest percentage population increase in El Dorado County occurred in the 1970s (www.census.gov/population/cencounts/ca190090.txt). These observations appear to contradict the statement that "... workers' exposure was more frequent, more regular, and lasted longer than we would expect in the community situation."

There appears to be a direct contradiction between 2 sentences in the discussion of fiber types, shapes and sizes on page 12. An unsupported and unreferenced statement is made that workplace exposures are more uniform than NOA because "... NOA exposures typically include a much wider range of asbestos fiber types, shapes and sizes as well as a large percentage of non-asbestos particles and/or

accessory minerals." This statement is directly followed by "Unfortunately, comparing fiber mineralogy and size distributions between exposures of asbestos workers and people exposed to NOA is impossible at this time—the historical data on worker exposures simply does not contain such detailed information."

"Wet" background exposure assumption: Additional data or information should be presented to support the assumption that background asbestos exposures during "wet" times are 1/10 of the exposures during dry periods. The current text refers to construction monitoring data in Figure 7 as "partial support" for the assumption that during the "wet" period "concentrations were an order of magnitude smaller but does not provide a detailed discussion of how these data were used to make the 1/10 assumption. It has been U.S. EPA Region 9's experience that exposure concentrations from soil disturbance activities during wet periods are similar to those during dry periods. Activity-based sampling at the Clear Creek Management Area off-road recreational area exhibited similar personal exposure monitoring concentrations during both dry and rainy seasons.

Toxicity profile citations. Many of the statements presented in the discussion are cited to the ATSDR Toxicity Profile on Asbestos, which contains a review of various experimental and observational studies on asbestos exposures and health effects. However, it would be more helpful to the reader if statements about the observations or conclusions from individual studies were referenced to the original publications themselves, not to a review publication.

Acceptable risk discussion (p. 14): Although stated in the quote, the discussion of acceptable risk from carcinogens should note that is an EPA policy applying to CERCLA (Superfund) risk management decisions.

The next paragraph says that these risks relate to "people being exposed for a specified length of time, *usually a lifetime...*". Actually, most Superfund risk assessments are based on a 30 year exposure duration using an RME (Reasonable Maximum Exposure) scenario [and occasionally a 9 year Central Tendency exposure scenario].

Inclusion of background exposures. Regarding the discussion on p. 32 of including background exposures into the consultation's risk assessment, Region 9 believes it <u>is</u> appropriate to include background exposures. In this community the background exposure is created by the same source as the activity-specific exposures, namely the presence of NOA in the community. Background exposures may be treated differently by U.S. EPA at CERCLA sites when those exposures are due to a different source than the contamination at the site.